

Volume 19 Index

Pages	Month (Issue No.)
1-58	January (1)
59-116	February (2)
117-174	March (3)
175-232	April (4)
233-298	May (5)
299-360	June (6)
361-418	July (7)
419-476	August (8)
477-534	September (9)
535-592	October (10)
593-650	November (11)
651-716	December (12)

Author Index

Abrass IB. Drugs: A Special Problem in the Treatment of the Elderly, 638
 Adkins PC. *See* Geelhoed GW
 Barnard J. *See* Greene JW
 Dunham WK. The ABCs of Exercise Physiology: A Foundation for Preventive Health Care (CME), 554
 Ebersold MJ, Marsh WR, Onofrio BM. Chemonucleolysis in the Treatment of Lumbar Disc Disease (CME), 337
 Eden AN. Treatment of Childhood Obesity, 315
 Ettinger LD. *See* Solomon DA
 Finlayson RE. Depression That Does Not Respond to Drugs (CME), 504
 Fisher JV. The Family Physician's Role in Managing Alcohol and Drug Abuse: A Response to Stephens's Decalogue, 129
 Flaker G, Munuswamy K. Evaluation of Syncope With Intracardiac Electrophysiologic Testing (CME), 453
 Geelhoed GW. Multiple System Failure in the Critically Injured Patient (CME), 75
 Geelhoed GW. The Use and Abuse of Systemic Antibiotics in Surgical Patients (CME), 391
 Geelhoed GW, Zimmerman JE, Adkins PC. Uses and Abuses of Albumin: Guidelines for Colloid Therapy, 585
 Goldenberg RL, Nelson KG,

Humphrey JL, Wayne JB. Mortality and Morbidity in the Perinatal Period, 435
 Grau RG. Management of Raynaud's Phenomenon (CME), 200
 Grauer K. Differentiating Between Aberrantly Conducted Beats and Ventricular Ectopy (CME), 85
 Greene JW, Barnard J. Recurrent Abdominal Pain in Childhood and Adolescence (CME), 256
 Holten KB, John PG. Sudden Death in Salicylate Overdose, 191
 Humphrey JL. *See* Goldenberg RL
 Jablonski CK. Amyotrophic Lateral Sclerosis (CME), 138
 James EJP. *See* Monzon CM
 John PG. *See* Holten KB
 Kansal PC. Regulation of Diabetes Mellitus With the Biostator, 490
 Katzenstein DA. The Sexual Transmission of Viral Infections (CME), 18
 Kendall AR. Benign Prostatic Hyperplasia: Medical Evaluation, Treatment, and Operative Indications (CME), 680
 Kenny JD, Ritter DA. The Intrauterine Growth-Retarded Infant (CME), 689
 Laws HL. The Current Role of Surgery in the Management of Duodenal Ulcer (CME), 383
 Marsh WR. *See* Ebersold MJ
 Mohammad AM. *See* Monzon CM
 Monzon CM, Mohammad AM, James EJP. Evaluation of Hemolysis in the Neonate (CME), 211
 Munuswamy K. *See* Flaker G
 Nelson KG. *See* Goldenberg RL
 Onofrio BM. *See* Ebersold MJ
 Orr JW Jr. The Laser in Gynecology (CME), 567
 Panush RS. All Aches Are Not Arthritis: Nonarticular Rheumatism, 375
 Pepine CJ. Clinical Use of Calcium-Channel Blockers in Cardiovascular Disease (CME), 13
 Petty TL. Chronic Obstructive

Pulmonary Disease Management (CME), 510

Quan MA. *See* Rodney WM
 Quinlan RW. A Structured Approach to Antenatal Ultrasound Examinations (CME), 611
 Ritter DA. *See* Kenny JD
 Rodney WM, Quan MA, Sakiyama R, Vincent C. The Low T₃ (Euthyroid Sick) Syndrome in the Elderly: A Practical Diagnostic Approach (CME), 463
 Sakiyama R. *See* Rodney WM
 Siegel RL. T and B Cell Abnormalities in Immunologic Diseases (CME), 264
 Solomon DA, Ettinger LD. Prophylaxis of Pulmonary Emboli: A Critical Assessment (CME), 330
 Stead EA Jr. The Cholesterol Controversy Continues, 249
 Susman JL. Problems in Thyroid Endocrinology (CME), 145
 Talley JH. A Useful Patient Handout in the Management of Depression, 280
 Vincent C. *See* Rodney WM
 Watts C. The Management of Ruptured Intervertebral Disc Disease by Chemonucleolysis, 667
 Wayne JB. *See* Goldenberg RL
 Zimmerman JE. *See* Geelhoed GW
Editorial Index
 American Medicine Transformed, 6
 Which Physicians Will Care for the Nation's Children? 68
 A Decalogue for the Management of Alcohol and Drug Abuse, 125
 Salicylate Poisoning, 184
 The Medical Supermarket: Futuristic or Decadent? 243
 Home Deliveries—Why? 315
 Testing, Antiknowledge, and Negating the Negative, 371
 American Medicine and the Enchanted Machine, 428
 The Man With a Renal Cyst, 487
 Using the Law for Treatment, 551

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Abrass IB. Drugs: A Special Problem in the Treatment of the Elderly, 638
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 Dunham WK. The ABCs of Exercise Physiology: A Foundation for Preventive Health Care (CME), 554
 Ebersold MJ, Marsh WR, Onofrio BM. Chemonucleolysis in the Treatment of Lumbar Disc Disease (CME), 337
 Eden AN. Treatment of Childhood Obesity, 315
 Ettinger LD. *See* Solomon DA
 Finlayson RE. Depression That Does Not Respond to Drugs (CME), 504
 Fisher JV. The Family Physician's Role in Managing Alcohol and Drug Abuse: A Response to Stephens's Decalogue, 129
 Flaker G, Munuswamy K. Evaluation of Syncope With Intracardiac Electrophysiologic Testing (CME), 453
 Geelhoed GW. Multiple System Failure in the Critically Injured Patient (CME), 75
 Geelhoed GW. The Use and Abuse of Systemic Antibiotics in Surgical Patients (CME), 391
 Geelhoed GW, Zimmerman JE, Adkins PC. Uses and Abuses of Albumin: Guidelines for Colloid Therapy, 585
 Goldenberg RL, Nelson KG,

Humphrey JL, Wayne JB. Mortality and Morbidity in the Perinatal Period, 435
 Grau RG. Management of Raynaud's Phenomenon (CME), 200
 Grauer K. Differentiating Between Aberrantly Conducted Beats and Ventricular Ectopy (CME), 85
 Greene JW, Barnard J. Recurrent Abdominal Pain in Childhood and Adolescence (CME), 256
 Holten KB, John PG. Sudden Death in Salicylate Overdose, 191
 Humphrey JL. *See* Goldenberg RL
 Jablonski CK. Amyotrophic Lateral Sclerosis (CME), 138
 James EJP. *See* Monzon CM
 John PG. *See* Holten KB
 Kansal PC. Regulation of Diabetes Mellitus With the Biostatator, 490
 Katzenstein DA. The Sexual Transmission of Viral Infections (CME), 18
 Kendall AR. Benign Prostatic Hyperplasia: Medical Evaluation, Treatment, and Operative Indications (CME), 680
 Kenny JD, Ritter DA. The Intrauterine Growth-Retarded Infant (CME), 689
 Laws HL. The Current Role of Surgery in the Management of Duodenal Ulcer (CME), 383
 Marsh WR. *See* Ebersold MJ
 Mohammad AM. *See* Monzon CM
 Monzon CM, Mohammad AM, James EJP. Evaluation of Hemolysis in the Neonate (CME), 211
 Munuswamy K. *See* Flaker G
 Nelson KG. *See* Goldenberg RL
 Onofrio BM. *See* Ebersold MJ
 Orr JW Jr. The Laser in Gynecology (CME), 567
 Panush RS. All Aches Are Not Arthritis: Nonarticular Rheumatism, 375
 Pepine CJ. Clinical Use of Calcium-Channel Blockers in Cardiovascular Disease (CME), 13
 Petty TL. Chronic Obstructive

Pulmonary Disease Management (CME), 510

Quan MA. *See* Rodney WM
 Quinlan RW. A Structured Approach to Antenatal Ultrasound Examinations (CME), 611
 Ritter DA. *See* Kenny JD
 Rodney WM, Quan MA, Sakiyama R, Vincent C. The Low T₃ (Euthyroid Sick) Syndrome in the Elderly: A Practical Diagnostic Approach (CME), 463
 Sakiyama R. *See* Rodney WM
 Siegel RL. T and B Cell Abnormalities in Immunologic Diseases (CME), 264
 Solomon DA, Ettinger LD. Prophylaxis of Pulmonary Emboli: A Critical Assessment (CME), 330
 Stead EA Jr. The Cholesterol Controversy Continues, 249
 Susman JL. Problems in Thyroid Endocrinology (CME), 145
 Talley JH. A Useful Patient Handout in the Management of Depression, 280
 Vincent C. *See* Rodney WM
 Watts C. The Management of Ruptured Intervertebral Disc Disease by Chemonucleolysis, 667
 Wayne JB. *See* Goldenberg RL
 Zimmerman JE. *See* Geelhoed GW
Editorial Index
 American Medicine Transformed, 6
 Which Physicians Will Care for the Nation's Children? 68
 A Decalogue for the Management of Alcohol and Drug Abuse, 125
 Salicylate Poisoning, 184
 The Medical Supermarket: Futuristic or Decadent? 243
 Home Deliveries—Why? 315
 Testing, Antiknowledge, and Negating the Negative, 371
 American Medicine and the Enchanted Machine, 428
 The Man With a Renal Cyst, 487
 Using the Law for Treatment, 551

The Medical Supermarket:
Futuristic or Decadent? Part II,
600
Five Aspects of the Healer, 663

Subject Index

Abdominal pain, recurrent. *See*
Recurrent abdominal pain in
childhood and adolescence
Aberrantly conducted beats
Ashman phenomenon, 89
atrial fibrillation, 95
caveats in diagnosis of, 93
compensatory pauses, 93
explanation of aberrancy, 85
recognition of, 87
regular wide-complex
tachydysrhythmias, 97
ventricular ectopy and, 85
Adolescents
recurrent abdominal pain, 256
Adult respiratory distress syndrome
multiple system failure and, 80
Aerobic exercise
physiologic benefits of, 558
Albumin, human
abuses, 586
uses, 585
Amyotrophic lateral sclerosis, 138
Angina
calcium-channel blockers, clinical
use of, 13
Antenatal ultrasound examination
amniotic fluid volume, 618
evaluating fetus for symmetry of
growth, 621
fetal gestational age, 620
fetal position, number, and
viability, 612
minimum standards, 611
placental evaluation, 619
screen for fetal developmental
anomalies, 625
Antibiotics, systemic
prophylactic use, 392
surgical infections, treatment of,
398
use and abuse in surgical patients,
391
Arrhythmias
calcium-channel blockers, clinical
use of, 17
Benign prostatic hyperplasia
diagnosis, 681
examination of patients with
prostatic symptoms, 682
signs and symptoms, 680
treatment, 682
urologic complications of
prostatism, 681
Biostator
regulation of diabetes mellitus, 490
Calcium-channel blockers, clinical

use of in cardiovascular disease
angina, 13
arrhythmias, 17
Cervical dysplasia
laser therapy, 569
Chemonucleolysis
chymopapain, mechanism of
action of, 668
chymopapain, pharmacology of,
668
compared with surgery, 670
complications of, 670
indications for, 670
lumbar disc disease, treatment of,
337, 667
results of, 670
Children. *See also* Intrauterine
growth retardation and Infant
mortality and morbidity
obesity, treatment of, 321
recurrent abdominal pain, 256
Cholesterol
atherosclerosis and, 249
diet and, 250
drugs and serum cholesterol, 250
exercise and, 251, 560
nervous system and, 251
Chronic obstructive pulmonary
disease
airflow limitation, 511
management, 515
pulmonary rehabilitation, 518
risk factors, 515
Condylomata
laser therapy, 577
Deep venous thrombosis
pulmonary emboli and, 330
Depression
electroconvulsive therapy, 508
management of, 280
refractoriness to drug treatment,
504
Depression management patient
handout, 281
Diabetes mellitus
Biostator, regulation with, 490
Drugs, use in treatment of elderly,
638
adverse effects, 640
specific drugs, 641
Elderly
low T_3 (euthyroid sick) syndrome,
463
use of drugs in treatment of, 638
Electroconvulsive therapy
treatment of depression, 508
Euthyroid sick syndrome. *See* Low
 T_3 (euthyroid sick) syndrome
Exercise physiology
aerobic exercise, physiologic
benefits of, 558
basics of, 554
health benefits, 560
maintenance of fluid intake, 559
types of training, 559

Hepatic insufficiency
multiple system failure and, 81

Immunologic diseases
B-cell abnormalities, 269
T-cell abnormalities, 264
Infant mortality and morbidity, 435
Intrauterine growth retardation
definition, 689
developmental follow-up, 698
etiology, 690
growth-retarded infant at birth,
694
management, 696
"Irreversible shock"
multiple system failure and, 78

Laser
gynecology, use in, 567
Low T_3 (euthyroid sick) syndrome
in the elderly, 463
Lumbar disc disease
chemonucleolysis, management
by, 337, 667
pathophysiology, 667

Multiple system failure, 75
acute renal failure, 79
adult respiratory distress
syndrome, 80
CNS failure and death, 81
hepatic insufficiency, 81
"irreversible shock," 78
multiple, progressive, or
sequential system failure, 82
organ substitution and the
definition of human life, 76
stress ulceration, 80
synergism and organ reserves, 76

Neonate, hemolysis in
acquired red-cell disorders, 215
characteristics of red cells in the
newborn, 211
congenital red-cell disorders, 216
indications and causes, 214
isoimmunization, 215
Nonarticular rheumatism
elbow, 377
fibrositis, 378
foot and ankle, 378
hand and wrist, 377
hip and thigh, 377

Obesity
childhood, treatment of, 321

Perinatal mortality and morbidity,
435
Premature ventricular contractions.
See Ventricular ectopy
Pulmonary emboli
prophylaxis of, 330

continued on page 710

Tagamet® brand of cimetidine

Before prescribing, see complete prescribing information in SK&F LAB CO. literature or *PDR*. The following is a brief summary.

Indications: Tagamet (brand of cimetidine) is indicated in the short-term treatment of active duodenal ulcer; in prophylactic use, at reduced dosage, to prevent recurrent duodenal ulcer in patients likely to need surgical treatment, such as those with a history of recurrence or complications and those with concomitant illness in whom surgery would constitute a greater than usual risk (limitation to this population is recommended because the consequences of use beyond one year of continuous Tagamet therapy are not known); in the short-term treatment of active benign gastric ulcer (there is no information concerning usefulness of treatment periods of longer than 8 weeks); and in the treatment of pathological hypersecretory disorders (i.e., Zollinger-Ellison syndrome, systemic mastocytosis and multiple endocrine adenomas). In active duodenal ulcer, concomitant antacids should be given as needed for relief of pain; however, simultaneous administration is not recommended.

Contraindications: There are no known contraindications to the use of Tagamet.

Precautions: While a weak antiandrogenic effect has been demonstrated in animals, Tagamet has been shown to have no effect on spermatogenesis, sperm count, motility, morphology or *in vitro* fertilizing capacity in humans.

In a 24-month toxicity study in rats at dose levels approximately 9 to 56 times the recommended human dose, benign Leydig cell tumors were seen. These were common in both the treated and control groups, and the incidence became significantly higher only in the aged rats receiving Tagamet.

Rare instances of cardiac arrhythmias and hypotension have been reported following the rapid administration of Tagamet HCl (brand of cimetidine hydrochloride) injection by intravenous bolus.

Symptomatic response to Tagamet therapy does not preclude the presence of a gastric malignancy. There have been rare reports of transient healing of gastric ulcers despite subsequently documented malignancy.

Reversible confusional states have been reported on occasion, predominantly in severely ill patients.

Tagamet has been reported to reduce the hepatic metabolism of warfarin-type anticoagulants, phenytoin, propranolol, chlorthalidone, diazepam, lidocaine and theophylline. Clinically significant effects have been reported with the warfarin anticoagulants; therefore, close monitoring of prothrombin time is recommended, and adjustment of the anticoagulant dose may be necessary when Tagamet is administered concomitantly. Interaction with phenytoin, lidocaine and theophylline has also been reported to produce adverse clinical effects.

Lack of experience to date precludes recommending Tagamet for use in pregnant patients, women of child-bearing potential, nursing mothers or children under 16 unless anticipated benefits outweigh potential risks; generally, nursing should not be undertaken in patients taking the drug since cimetidine is secreted in human milk.

Decreased white blood cell counts have been reported in Tagamet-treated patients who also received drugs and/or treatment known to produce neutropenia.

Adverse Reactions: Diarrhea, dizziness, somnolence, headache, rash, mild gynecomastia. Reversible arthralgia, myalgia and exacerbation of joint symptoms in patients with preexisting arthritis have been reported. Reversible confusional states (e.g., mental confusion, agitation, psychosis, depression, anxiety, hallucinations, disorientation), predominantly in severely ill patients, have been reported. Reversible impotence in patients with pathological hypersecretory disorders receiving Tagamet, particularly in high doses, for at least 12 months, has been reported. Decreased white blood cell counts in Tagamet-treated patients (approximately 1 per 100,000 patients), including agranulocytosis (approximately 3 per million patients), have been reported, including a few reports of recurrence on challenge. These patients generally had serious concomitant illnesses and received drugs and/or treatment known to produce neutropenia. Thrombocytopenia (approximately 3 per million patients) and a few cases of aplastic anemia have also been reported. Increased serum transaminase and creatinine, as well as rare cases of fever, interstitial nephritis and pancreatitis have been reported. Reversible adverse hepatic effects, cholestatic or mixed cholestatic-hepatocellular in nature, have been reported rarely. Because of the predominance of cholestatic features, severe parenchymal injury is considered highly unlikely. A single case of biopsy-proven periportal hepatic fibrosis in a patient receiving Tagamet has been reported.

How Supplied: Pale Green Tablets: 200 mg, tablets in bottles of 100; 300 mg, tablets in bottles of 100 and Single Unit Packages of 100 (intended for institutional use only); 400 mg, tablets in bottles of 60.

Liquid: 300 mg./5 ml., in 8 fl. oz. (237 ml.) amber glass bottles.

Injection: 300 mg./2 ml. in single-dose vials and in 8 ml. multiple-dose vials, in packages of 10, and in single-dose, prefilled disposable syringes.

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INDEX TO VOLUME 19 *continued from page 707*

- Raynaud's phenomenon
 - calcium-channel blockers, 205
 - diagnosis and evaluation, 202
 - pathophysiology, 201
 - therapy, conventional, 202
 - vasodilators, experimental, 206
- Recurrent abdominal pain in
 - childhood and adolescence
 - definition, 256
 - familial and psychosocial factors, 259
 - history, 257
 - incidence, 256
 - laboratory examination, 259
 - management, 262
 - nonorganic pain, 257
 - organic causes, 257
 - physical examination, 259
 - prognosis, 263
- Renal failure, acute
 - multiple system failure and, 79
- Ruptured lumbar intervertebral disc disease. *See* Lumbar disc disease
- Salicylate overdose
 - sudden death, 191
 - treatment of, 192
- Stress ulceration
 - multiple system failure and, 80
- Sudden death
 - salicylate overdose, 191
- Syncope, evaluation with
 - electrophysiologic testing
 - conduction system, 453
 - sinus node function, 456
 - syncope caused by arrhythmias, 461
- Thyroid endocrinology
 - dysfunction in the acutely ill, 157
 - dysfunction in the elderly, 157
 - physiology, 145
 - screening, 155
 - testing, pitfalls of, 152
 - tests, 149
- Ulcer, duodenal
 - surgery, 383
- Ultrasound
 - in antenatal examination, 611
- Vaginal dysplasia
 - laser therapy, 572
- Vagotomy
 - duodenal ulcer and, 384
- Ventricular ectopy
 - aberrantly conducted beats and, differentiating between, 85
- Viral infections, sexual transmission of
 - cytomegalovirus, 22
 - hepatitis B virus, 23
 - herpes genitalis, 18
- Vulvar dysplasia
 - laser therapy, 572

